

SAFETY DATA SHEET

PRODUCT NAME: Liquid PedvaxHIB™**Page:** 1/6**Revision** 8-Oct-2007

1. Product and Company Identification

Manufactured/Supplied by MERCK & CO., INC.
One Merck Drive
Whitehouse Station, NJ 08889-0100
(908) 423-1000

Label Name Liquid PedvaxHIB™

Chemical Name Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)

Synonyms Not available

Material Product Number No. 4897 — A box of 10 single-dose vials of liquid vaccine
NDC 0006-4897-00

Intended Use Vaccine indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age.

2. Composition/Information on Ingredients

<u>Component</u>	<u>Molecular Formula</u>	<u>Molecular weight</u>	<u>CAS Number</u>	<u>Percent (%)</u>
Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	Not available	Not available	Not available	<0.1
Aluminum hydroxyphosphate sulfate	Not available	Not available	20257-20-9	<0.1
Inactive Ingredients	- - -	Not available	- - -	>99.9

EC Label Not classified.

3. Hazards Identification

Appearance Slightly opaque white liquid

Label Text CAUTION!
VACCINE

Emergency Overview Avoid direct contact with skin and eyes. Wash thoroughly after handling. No immediate hazard from intact vials.

Potential Health Effects See Section 11 for detailed information.

4. First Aid Measures

<u>Eye Contact</u>	In case of contact, flush eyes with plenty of water. Get medical attention if symptoms occur.
<u>Skin Contact</u>	Wash with soap and water. Get medical attention if irritation develops.
<u>Inhalation</u>	If inhaled, remove to fresh air. Get medical attention if symptoms appear.
<u>Ingestion</u>	Do NOT induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms appear.
<u>Notes to physician</u>	Treat supportively and symptomatically. For additional guidance refer to the current prescribing information or the local poison control center.

5. Fire Fighting Measures

<u>Flash Point</u>	Not applicable
<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available
<u>Oxidizing Properties</u>	Not available
<u>Combustibility Information</u>	Not available
<u>Dust Explosivity Information</u>	Not applicable
<u>Shock Sensitivity</u>	Not applicable
<u>Fire/Explosion Hazards</u>	None known.
<u>Special Fire Procedures</u>	No special procedures.
<u>Extinguishing Media</u>	In case of fire, use water spray (fog), foam, dry chemical, or CO ₂ .
<u>Hazardous Decomposition Products</u>	None known.

6. Accidental Release Measures

<u>Personal Precautions</u>	See Section 8 for Personal Protective Equipment. Contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures (Section 5).
<u>Methods for cleaning up</u>	Contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. See Section 13 for Waste Disposal Information.

For additional assistance in the U.S., CHEMTREC provides a toll-free Hotline for chemical emergencies regarding spills, leaks, exposure or accidents: 1-800-424-9300.
For emergency calls from outside the U.S.: 1-703-527-3887

7. Handling and Storage

Handling

Avoid direct contact with skin and eyes. Wash thoroughly after handling.

Storage

In the absence of specific storage recommendations, keep container in a cool, well-ventilated area. Keep container tightly closed.

8. Exposure Controls/Personal Protection

Exposure Guidelines

<u>Component</u>	<u>OSHA Permissible Exposure Limit (PEL)</u>	<u>ACGIH Threshold Limit Value (TLV)</u>	<u>Merck Exposure Control Limit (ECL) or PB-ECL Category</u>
Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	Not established	Not established	PB-ECL 3*
Aluminum hydroxyphosphate sulfate	Not available	Not available	Not available
Inactive Ingredients	Not available	Not available	Not available

*Corresponds to 10-100 ug/m³ as an 8-hr TWA.
PB-ECL category is an internal Merck control band.

Engineering Controls

Adequate ventilation should be provided if there is risk of aerosol formation. None required when handling sealed vials.

Personal Protective Equipment

Eye/Face Protection

Safety glasses with side shields should be worn when handling bulk liquid formulation or filling vials. None required when handling sealed vials.

Skin Protection

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. None required when handling sealed vials.

Respiratory Protection

No respiratory protection required when handling bulk liquid formulation or sealed vials. As an adjunct to engineering controls, use an approved, properly fitted, powered air purifying respirator, or respirator of equivalent or greater protection if the potential exists for exposure to airborne aerosols.

Additional Protective Equipment

Work uniform or laboratory coat.

9. Physical and Chemical Properties

Appearance

Slightly opaque white liquid

Odor/Threshold Limit

Not available

pH

Not available

Boiling Point

Not available

Melting Point

Not available

Flash point

Not applicable

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<u>Flammable Limits (% in air)</u>	Not applicable
<u>Autoignition Temperature</u>	Not available
<u>Solubility</u>	Not available
<u>Partition Coefficient</u>	Not available
<u>Specific Gravity</u>	Not available
<u>Vapor Density</u>	Not available
<u>Vapor Pressure</u>	Not available
<u>Volatility Component</u>	Not available

10. Stability and Reactivity

<u>Stability</u>	Not available
<u>Conditions to Avoid</u>	Not available
<u>Incompatibility</u>	Not available
<u>Hazardous Polymerization</u>	Not available
<u>Hazardous Decomposition Products</u>	None known.

11. Toxicological Information

<u>Routes of Entry</u>	Ingestion:	No.
	Inhalation:	Yes
	Skin Contact:	No.

Toxicity Data

<u>Component</u>	<u>Test</u>	<u>Species</u>	<u>Route</u>	<u>Result</u>
Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)	Not available	Not available	Not available	Not available
Aluminum hydroxyphosphate sulfate	Not available	Not available	Not available	Not available

Effects of Acute Exposure

<u>Eye contact</u>	Not available
<u>Skin contact</u>	Not available
<u>Inhalation</u>	Not available
<u>Ingestion</u>	Not available

Effects of Chronic Exposure

This compound is a vaccine indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age. PedvaxHIB showed no adverse effects in general safety testing conducted in guinea pigs and mice. Because the lipopolysaccharide (LPS) contained by OMPC has the capacity to elicit a pyrogenic response when the LPS is biologically accessible, pyrogenicity tests through intramuscular and intravenous routes were developed and are conducted in rabbits. Release criteria require that no significant temperature rise is observed in these tests. PedvaxHIB has not been evaluated for its carcinogenic, mutagenic potential, or the potential to impair fertility.

The most frequently reported (>1%) adverse reactions, without regard to causality, were fever (>101°F), irritability, sleepiness,

injection-site pain/soreness, injection-site erythema (<2.5 cm diameter), injection-site swelling/induration (<2.5 cm diameter), unusual high-pitched crying, prolonged crying (>4 hours), diarrhea, vomiting, crying, pain, otitis media, rash, and upper respiratory infection.

Carcinogen Designation

Not listed as a carcinogen by OSHA, NTP or IARC.

Medical Conditions Aggravated by Overexposure:

Not available

12. Ecological Information

Environmental Effects

Not available

Ecotoxicity Data

Component

Species

Period

Result

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)

Not available

Not available

Not available

Aluminum hydroxyphosphate sulfate

Not available

Not available

Not available

Inactive Ingredients

Not available

Not available

Not available

Environmental Fate

Not available

13. Disposal Considerations

Waste Disposal Information

Avoid contact of spilled material and runoff with soil and surface waterways. Dispose of or treat all spill residues including contaminated soils following all applicable regulations.

14. Transport Information

Shipping Description

U.S. DOT

Not regulated.

IATA/ICAO

Not regulated.

IMO

Not regulated.

ADR/RID

Not regulated.

15. Regulatory Information

U.S. Federal Regulations

Not hazardous per OSHA Hazard Communication Standard criteria (29 CFR 1910.1200)

State Regulations

Not available

International Regulations

Not classified as Dangerous according to the Dangerous Substances Directive (DSD).

16. Other InformationRevision:

10/8/2007.

MSDS Coordinator:

1-908-423-7903
Merck & Co., Inc.
Two Merck Drive
P.O. Box 200, WS2W-13
Whitehouse Station, NJ 08889-0200
U.S.A.

Disclaimer:

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